External Counterpulsation (ECP) Therapy (#CAG-00002N)

Meeting Report

Subject: Enhanced external counterpulsation therapy
Purpose: Meet with Vasomedical, Inc., to review and discuss their clinical trial on enhanced external counterpulsation
Date: December 16, 1998
Place: 10:00, HCFA conference room B

Participants:

HCFA: Grant Bagley, M.D., Vilis Kilpe, M.D., Mitch Burken, M.D., Ron Milhorn, Joyce Eng, Kimberly Pugh, Dorothy Honneman, Kathy Linstromberg

NON-HCFA: Anthony Viscusi, President and CEO, Vasomedical, Inc.; Anthony E. Peacock, VP of Clinical Affairs, Vasomedical, Inc; Bruce L. Fleishman, M.D., President of Medical Staff, Grant/Riverside Methodist Hospitals, Grant campus, Columbus, Ohio; Lawrence E. Crawford M.D., Assistant Professor of Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; Neal Stine, VP for Market Development, Vasomedical, Inc.; Judy Hickey, President, Princeton Reimbursement Group.

Summary:

Vasomedical presented the data from their recently-completed clinical trial on the use of enhance external counterpulsation (EECP). An article outlining their data and findings has been accepted for publication by a peer-reviewed medical journal.

The major results of the study, the Multicenter Study of Enhanced External Counterpulsation (MUST-EECP) indicated that the use of this therapy on patients with stable angina (Canadian Cardiovascular Society Class I, II, or III) resulted in improved functional status in more than 70% of patients.

Presentation/Discussion:

Drs. Fleishman and Crawford presented a summary of previous research and the results of the MUST-EECP clinical trial. Noting that previous studies suffered from small numbers of patients and use of a single site, the MUST-EECP trial enrolled 139 patients (137 of which were evaluable) in seven medical centers in a randomized, sham-controlled, double-blinded trial.

The parameters of the study included: (1) exercise ability, measured by exercise duration and time to ST-segment depression; (2) clinical status, measured by frequency of anginal episodes and intake of nitroglycerin; (3) adverse experiences, measured by physical exams, lab tests, and daily questions; and (4) statistical analysis, measured by P-values calculated for between-group differences using Cochan-Mantel-Haenszel Chi-Squared tests for ordered categories stratified by investigator.

Inclusion criteria included patients with angina Class I, II, or III,

and evidence of coronary artery disease evidenced by: (1) angiographic evidence of 70% or greater stenosis; or (2) documented evidence of myocardial infarction; or (3) positive nuclear stress test plus a positive exercise test within a 4-week baseline period.

Exclusion criteria included: (1) unstable angina; (2) myocardial infarction or coronary artery bypass in the prior 3 months; (3) cardiac catheterization in the prior 2 weeks; (4) arrhythmias (AF or VPBs) interfering with triggering of EECP; (5) marked baseline ECG abnormalities limiting interpretation (digoxin use, LVH with strain, LBBB); (6) permanent pacemaker or defibrillator; (7) congestive heart failure with left ventricular ejection fraction less than 30%); (8) significant valvular heart disease; (9) severe symptomatic peripheral vascular disease; (10) history of varicosities, deep vein thrombosis, phlebitis and/or stasis ulcer; (11) ambulatory BP above 180/100 mm Hg; (12) bleeding diathesis, Coumadin use with INR greater than 2.0; (13) inability to undergo treadmill tests; (14) non-bypassed left main with greater than 50%; (15) enrollment in a cardiac rehabilitation program; or (16) participation in another research study.

The randomization resulted in patients closely matched between active and sham treatment in age, ethnicity, angina class, previous infarcts, bypass or angioplasties. However, in all cases the active treatment group were in poorer health or condition the control group.

The changes reported in the active treatment versus the sham treatment groups were statistically significant in time to ST-segment depression and in angina counts. Differences in exercise times and nitroglycerin use were not significantly different. The investigators noted that the former has been seen in other clinical trials on ischemic patients, and is believed to result from limitations on exercise tolerance by non-anginal symptoms, such as fatigue and shortness of breath. The lack of change in nitroglycerin use was also expected, since most patients had been taking the drug prophylactically for some time.

Adverse events appeared mostly device-related, primarily skin abrasions on the legs and pain in the legs and back caused by the treatment. Although 47 of the 95 events reported were considered device-related, only 5 patients withdrew from the study due to leg complaints.

The investigators emphasized that the study was not designed to identify patient categories, but rather to demonstrate its effectiveness in treating patients with stable angina and proven coronary artery disease. Additional study is needed to determine whether this treatment is effective in patients with different anginal syndromes, magnitude of coronary artery disease and/or background medications. Comparison of EECP to medical therapy and revascularization procedures has not been done and is subject to future clinical trials.

Evaluation:

Despite the limitations of the study, it demonstrated EECP's medical effectiveness in reducing angina and extending time to ischemia for over one year following the course of treatment for those patients with symptomatic coronary artery disease.

Next steps/follow-up items:

Prepare decision memorandum and draft instruction allowing limited coverage for this procedure.

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